UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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| In re ASTRAZENECA PLC SECURITIES LITIGATION | : | Case No. 1:21-cv-00722-JPO |
| | : | CLASS ACTION |
| | : | Oral Argument Requested |

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT**

POMERANTZ LLP
Jeremy A. Lieberman
Murielle J. Steven Walsh
Eric D. Gottlieb
600 Third Avenue, 20th Floor
New York, NY 10016
Telephone: 212/661-1100
917/463-1044 (fax)

ROBBINS GELLER RUDMAN
& DOWD LLP
Samuel H. Rudman
Alan I. Ellman
William J. Geddish
Magdalene Economou
58 South Service Road, Suite 200
Melville, NY 11747
Telephone: 631/367-7100
631/367-1173 (fax)

*Attorneys for Lead Plaintiffs*

(*Additional Counsel on Signature Page*)

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**TABLE OF ABBREVIATIONS**

| Abbreviation | Description |
|---|---|
| AC | Amended Complaint for Violations of the Federal Securities Laws, filed on July 12, 2021 (ECF No. 42), referenced as "¶" |
| ADS | American Depositary Share |
| Alexion | Alexion Pharmaceuticals, Inc. |
| App'x B | Appendix B to Defendants' Memorandum of Law in Support of Their Motion to Dismiss the AC (ECF No. 46-2) |
| AZD1222 | A recombinant adenovirus Covid-19 vaccine developed by Oxford and AstraZeneca, previously known as "ChAdOx1 nCoV-19," subsequently referred to as "COVID-19 Vaccine AstraZeneca," and now known as "Vaxzevria" |
| AZN, AZ, or the Company | Defendant AstraZeneca plc |
| CEO | Chief Executive Officer |
| CFO | Chief Financial Officer |
| CHMP | The European Medicines Agency's Committee for Medicinal Products for Human Use |
| Class Period | The period between June 15, 2020 and January 29, 2021, inclusive |
| COV002 | Phase II/III clinical trial in the UK for AZD1222 |
| Covid or Covid-19 | Coronavirus disease 2019, an infectious disease caused by the SARS-CoV-2 virus |
| Defendants | AZN, Pascal Soriot, Marc Dunoyer, and Menelas Pangalos |
| DSM | Data and Safety Monitoring |
| Dunoyer | Defendant Marc Dunoyer, AZN's CFO and a Director of AZN at all relevant times |
| EC | European Commission |
| EIVA | Europe's Inclusive Vaccine Alliance |
| EUA | Emergency Use Authorization |
| Exchange Act | Securities Exchange Act of 1934, 15 U.S.C. §78a *et seq.* |
| FDA | U.S. Food and Drug Administration |
| Individual Defendants | Pascal Soriot, Marc Dunoyer, and Menelas Pangalos |
| LD/SD | Lower dose/standard dose regimen of Phase II/III clinical trial |

| Abbreviation | Description |
|---|---|
| Lead Plaintiffs | Lead Plaintiffs Nuggehalli Balmukund Nandkumar and Wayne County Employees' Retirement System |
| MTD or Motion | Defendants' Memorandum of Law in Support of Their Motion to Dismiss the AC (ECF No. 46) |
| Operation Warp Speed | A public-private partnership to facilitate and accelerate the development, manufacturing, and distribution of Covid vaccines, therapeutics, and diagnostics |
| Oxford | University of Oxford, including the Jenner Institute and the Oxford Vaccine Group |
| Pangalos | Defendant Menelas Pangalos, AZN's Executive Vice President of Biopharmaceuticals Research & Development and Chief Scientist at all relevant times |
| Plaintiffs | Lead Plaintiffs Nuggehalli Balmukund Nandkumar and Wayne County Employees' Retirement System, and Additional Plaintiff Vladimir Zhukov |
| PSLRA | Private Securities Litigation Reform Act of 1995, 15 U.S.C. §78u-4 *et seq.* |
| Rule 9(b) | Federal Rule of Civil Procedure 9(b) |
| Rule 10b-5 | 17 C.F.R. §240.10b-5 |
| Rule 12(b)(6) | Federal Rule of Civil Procedure 12(b)(6) |
| SD/SD | Standard dose/standard dose regimen of Phase II/III clinical trial |
| SEC | U.S. Securities and Exchange Commission |
| Section 10(b) | Section 10(b) of the Exchange Act |
| Section 20(a) | Section 20(a) of the Exchange Act |
| Soriot | Defendant Pascal Soriot, AZN's CEO and a Director of AZN at all relevant times |
| STIKO | Standing Committee on Vaccination at Germany's Robert Koch Institute |
| Tracy Decl. | Declaration of Marques S. Tracy, executed September 27, 2021 (ECF No. 47) |
| UK | United Kingdom |
| U.S. | United States of America |
| Walsh Decl. | Declaration of Murielle J. Steven Walsh, executed December 10, 2021 |
| WHO | World Health Organization |

## PRELIMINARY STATEMENT

As the Covid pandemic sent shockwaves of fear across the globe in the spring of 2020, several pharmaceutical companies attempted to develop vaccines to combat the virus. AZN was one of those companies, and its intentions at the outset were presumably laudable. But good intentions do not provide license to defraud investors.

In April 2020, AZN partnered with Oxford to develop a potential recombinant adenovirus vaccine for Covid, later called AZD1222. As worldwide attention focused on AZN's vaccine trials, Defendants publicly discussed the progress they were making to develop the vaccine and touted how their trials were studying the efficacy of their vaccine candidate on people over 55 years of age, who were at heightened risk of severe, and potentially fatal, cases of Covid. Defendants, however, misrepresented facts regarding the AZD1222 trials and failed to disclose problems that had arisen, including a dosing error that Defendants discovered ***before the Class Period even began***.

On November 23, 2020, AZN announced the results of an interim analysis of its Phase II/III AZD1222 trials. The announcement immediately raised questions among analysts and industry experts. AZN disclosed that the interim analysis involved two smaller-scale trials in disparate locales (the UK and Brazil) that, for unexplained reasons, employed two different dosing regimens. One clinical trial provided patients a half dose of AZD1222 followed by a full dose, while the other trial provided two full doses. Counterintuitively, AZN claimed that the half-dose regimen was substantially more effective at preventing Covid – at 90% efficacy – than the full-dose regimen, which had achieved just 62% efficacy.

In the days that followed, additional revelations were made regarding problems with the AZD1222 clinical trials. The differing dosing regimens were revealed to be due to a manufacturing error, rather than trial design. AZN and Oxford acknowledged that they knew about the dosing error by no later than June 5, 2020. Critically, the half-dose regimen had not been tested in people over

the age of 55 at all, and the number of 55+ subjects in the full-dose regimen was so small as to be insufficient to measure efficacy – despite the fact that this population was the most vulnerable to Covid, and Defendants had specifically said they were testing this age group.

Ultimately, the half-dose regimen was rejected by UK regulators, who said the data did not support the finding of 90% efficacy. And AZD1222 has never been approved for emergency use authorization ("EUA") in the U.S., and likely never will, as AZN's competitors have cornered that market. Moreover, AZN was lambasted for its lack of transparency about the trials, which fuels vaccine skepticism and might lead to large swaths of the population refusing vaccination.

Defendants argue that Plaintiffs are improperly critiquing AZN's trial design and interpretation of trial results. But Defendants' failure to disclose, *inter alia*, the manufacturing error, the protocol change, and the insufficient number of 55+ trial subjects to measure efficacy is actionable because Defendants put AZN's conduct of the trials at issue by making positive statements about the trials, the trial design, and the testing of 55+ subjects. Defendants knew about, or recklessly disregarded, these concealed facts because AZN sought approval from its regulator to change the protocol due to the manufacturing error, and they spoke positively about testing on 55+ trial subjects repeatedly – creating the misleading impression that the trials were able to assess efficacy in the 55+ population. Defendants' other arguments concerning falsity, scienter, and loss causation likewise fail. Accordingly, Defendants' Motion should be denied.

## STATEMENT OF FACTS

### A. The Covid Pandemic and the Company

In early January 2020, the WHO announced the discovery of a new coronavirus strain in China, later called Covid-19 or Covid, which causes a variety of adverse symptoms in victims, including, in some cases, a severe acute respiratory illness that can be life threatening. ¶20. The world-wide devastation caused by Covid drove an unprecedented campaign by governments and

biopharmaceutical companies to develop treatments and vaccines for the virus. ¶23.

The FDA slashed regulatory hurdles and employed its EUA powers to speed up drug development, dramatically shortening the timeframe in which new drugs for Covid could be brought to market – from approximately 15-16 years to less than one. *Id.* These emergency measures increased the importance for companies developing Covid vaccine candidates to communicate honestly and transparently with governments, investors, and the public, and to adhere to the highest standards of safety and good clinical practices. ¶25. Because Covid vaccines would ultimately be administered to hundreds of millions of people, and vaccine hesitancy was pervasive due to the regulatory shortcuts taken to get a potential vaccine to market, it was imperative that the drugs were both safe and effective and accepted as such by target populations who may be skeptical. ¶¶27, 69.

AZN is primarily known for its development of drugs to treat cancer, asthma, and other chronic conditions, and has not historically specialized in vaccine development. ¶19. But in April 2020, AZN partnered with Oxford to develop AZD1222. ¶30. According to an April 30, 2020 press release, "AstraZeneca would be responsible for development and worldwide manufacturing and distribution of the vaccine." ¶31. Volunteers for the first clinical trial were recruited and screened in March 2020, and a Phase I trial was launched the following month. ¶30.

In May 2020, the U.S. government awarded AZN up to $1.2 billion for the development and manufacturing of the vaccine in exchange for 300 million doses. The U.S. set conditions on its investment, emphasizing enrolling older adults[1] and people with comorbidities in the vaccine trials because they are more vulnerable to the effects of Covid. ¶35. Although AZN announced that it would manufacture the vaccine at no profit during the course of the pandemic, expenses of the vaccine would be offset by grants from governments and international organizations. ¶36.

At the time, analysts pointed to the potential for a future commercial opportunity if re-

[1] Adults over the age of 55 are considered the most high-risk age group for Covid. *See, e.g.*, ¶¶5, 89, 96.

vaccination was required post-pandemic. For example, one analyst noted that "AZN does expect to make a profit post-pandemic. Should the vaccine evolve into a seasonal flu-like immunisation programme, the economics would be 'attractive.'" *Id.* "AstraZeneca has long said it would strive to eventually make a profit on the vaccine," and, in fact, AZN recently announced that it would "shift away from a nonprofit approach to the vaccine starting in 2022," and that it expected to record some revenues related to the vaccine beginning in the fourth quarter of 2021, thus "ending a period in which it had pledged to roll out the shots at cost during the pandemic." Walsh Decl. Ex. A at 1.

### B. Prior to the Class Period, Defendants Were Aware of a Dosing Error that Had Not Been Included in Their Original Trial Design

Prior to the Class Period, Defendants knew of a serious flaw in their trials. ¶¶5, 42. Specifically, a contract manufacturer had under-predicted the dose of the vaccine by half in the UK trial. ¶81. The dosing error was initially identified after a trial investigator noticed that volunteers were not having much of an inflammatory response to the vaccine, prompting the researchers to question their vaccine supply and find that they had miscalculated the dose. *Id.* Thus, the half-dosing regimen was not part of the original trial design, but rather forced upon AZN as a result of the manufacturing error. *Id.*

AZN knew of this error prior to the Class Period, when both AZN and Oxford notified health regulators, but not the public, about the dosing error. *Id.* AZN and Oxford then amended the study protocol to include recipients of this regimen (the "lower dose/standard dose" or "LD/SD" regimen or cohort) in the trial, in addition to recipients of two standard doses (the "standard dose/standard dose" or "SD/SD" regimen or cohort). ¶¶42, 78. The protocol was amended on June 5, 2020, less than two weeks before the start of the Class Period, resulting in enrollment of two distinct groups with different dosing regimens with no pause in enrollment, despite the fact that the trial was not intended to test different dosing cohorts. ¶¶42, 83. The LD/SD cohort was enrolled over 11 days

between May 31 and June 10, 2020. ¶42.

### C. Defendants Failed to Test the LD/SD Regimen on People Over 55

Significantly, the LD/SD cohort did not include any subjects older than 55 years of age. ¶¶42, 82. This was a glaring deficiency given that population's vulnerability to severe illness or death from Covid. *Id.* Indeed, the fact that the LD/SD cohort was the only cohort that showed robust efficacy (at 90%) was likely due to the exclusion of more vulnerable subjects. *See, e.g.*, ¶¶82, 86, 89. As the *Daily Mail* reported on November 26, 2020, "the 90% efficacy of the LD/SD cohort was being challenged by experts because of the small number of people it was tested on . . . and none of the volunteers were over 55 years of age, the most high-risk age group for Covid." ¶¶95-96. The *Daily Mail* also criticized the SD/SD cohort because it "appears to include few participants over the age of 55, even though the vaccine is being targeted at elderly people." ¶98.

### D. Defendants Touted AZD1222's Positive Trial Results but Omitted Material Facts Undermining the Reliability of Those Results

Defendants could have chosen to stay silent about the AZD1222 trials during the Class Period, given the uncertainty created by the dosing error and their knowledge that the trials were based in part on data that effectively excluded a key target population for their vaccine. Instead, Defendants repeatedly made positive statements regarding both the trials and their results throughout the Class Period, while omitting material adverse facts concerning the manufacturing error, the protocol change, and the dearth of subjects older than 55.[2]

The Class Period begins on June 15, 2020, when Defendants issued a press release announcing an agreement with the EIVA to supply up to 400 million doses of AZD1222. Despite, knowing that the Phase II/III trial suffered from a manufacturing error that necessitated a protocol

[2] Generally, Defendants' misstatements fall into one or more of the following categories: (1) statements that the Phase II/III trials would include participants of different ages and/or older participants, which implied that the number of older participants was sufficient to be studied (¶¶47, 50, 53-54, 70, 72, 76); (2) statements that discuss the status of the Phase II/III trials or the trial results (¶¶44, 49-52, 57, 67, 74-75); (3) statements that AZN was committed to the highest safety standards in the development of the vaccine (¶¶60-61, 63, 67, 73); and (4) a statement that AZN would submit its vaccine for approval only after a single Phase III study (¶63).

change, Defendants touted "the start of a Phase II/III UK trial of AZD1222 in about 10,000 adult volunteers" launched by Oxford the previous month. ¶44.

On July 20, 2020, AZN issued a press release regarding its ongoing AZD1222 clinical trials that, among other things, quoted Defendant Pangalos, who touted the Phase II/III trials' measurement of safety and immune responses in "different age ranges," as follows:

> ***Late-stage Phase II/III trials are currently underway in the UK, Brazil and South Africa*** and are due to start in the US. Trials will determine how well the vaccine will protect from the COVID-19 disease and measure safety and immune responses ***in different age ranges*** and at various doses. ¶47.[3]

On July 30, 2020, AZN announced the advancement to late stage trials, including participants "in different age ranges." ¶50. Similarly, during a conference call the same day, Pangalos made additional positive statements about the trial design and the data surrounding the study, including that the study "remain[ed] on track" (¶52), and that the data was derived from elderly and other at-risk patients. ¶54. In response to an analyst asking for "comment to give us timing at all when you may have some data on elderly . . . patients," Pangalos stated, "So data on different age groups is coming from the Phase I study and from the Phase II part and the Phase III study we're running in the U.K., and we're getting that data in on a weekly basis." *Id.*

On August 14, 2020, AZN announced that it had finalized an agreement with the EC to supply 400 million doses of AZD1222, and stated that "[c]linical development of AZD1222 is progressing globally with late-stage Phase II/III trials ongoing in the UK and Brazil[.]" ¶57. Then, on October 26, 2020, AZN announced that AZD1222 had produced a similar immune response in older and younger adults, and that adverse responses to the vaccine among the elderly were also found to be lower, stating: "It is encouraging to see immunogenicity responses were similar between older and younger adults and that reactogenicity was lower in older adults, where the COVID-19

[3] Unless otherwise indicated, emphasis is added and internal quotations and citations are omitted.

disease severity is higher." ¶70; *see also id.* n.2 (defining immunogenicity and reactogenicity). The price of AZN ADSs rose more than 2% on this news. ¶70.[4]

In a November 5, 2020 Form 6-K and during an earnings call that day, Defendants reiterated that their vaccine created positive immunogenetic responses in the older patient population, similar to those found in younger adults, which implied that the Phase II/III trials were able to assess efficacy in older patients and it was effective for that demographic:

- "[During the period,] [d]ata on immunogenicity and safety of in [sic] older adults was presented at IDWeek showing AZD1222 has an acceptable tolerability profile and is immunogenic in adults above 18 years of age, ***including older adults***. Stronger immune responses were shown after a second dose given one month apart, ***across all adult age ranges. Local and systemic reactions were lower in older adults than younger adults (<55 years) and reactions were lessened after the second dose***." ¶72 (quoting November 5, 2020 Form 6-K).
- During the November 5, 2020 earnings call, Pangalos reiterated that AZN's study included data on elderly patients and patients over the age of 55, stating "data [] showed that ***the immune response in the 56 to 69 year olds and 69 and 70 and above looks very similar to the response of the 18 to 55 year olds. In that regard, we're feeling good about the immunogenicity in all the age groups that we're testing***." ¶76.

These statements led investors to believe that AZN's vaccine trials included a sufficient number of subjects 55 and older to be studied. But the facts belie these statements because: (i) AZN experienced a manufacturing error and adopted the LD/SD regimen as a result, and did not include anyone over the age of 55 in this cohort (¶82); and (ii) the SD/SD regimen included so few older patients that efficacy in the 55+ population could not even be assessed due to insufficient data. ¶¶105, 108, 113, 119-121.

Defendants also made false statements about AZN's commitment to safety in connection with developing AZD1222. In response to "an increasing number of questions around the safety and availability of vaccines" to fight Covid, Defendants stated that "the Company was committed to 'the

[4] The price of AZN ADSs frequently rose on positive AZD1222-related news. For example, in June 2020, it rose on news of an agreement with EIVA. ¶44. In July 2020, it rose on the leaking of early positive data from the Phase I/II studies. ¶¶45, 46, 55. And in August 2020, it rose on reports that the President was considering issuing an EUA for the AZN Covid vaccine prior to the November 2020 presidential election. ¶59.

highest safety standards' and adherence to 'the highest scientific and clinical standards.'" ¶60. That announcement quoted Defendant Soriot as stating: "[I] want to reiterate my commitment that we are putting science and the interest of society at the heart of our work. We are moving quickly but without cutting corners, and regulators have clear and stringent efficacy and safety standards for the approval of any new medicine, and that includes this potential COVID-19 vaccine." *Id.*[5] Similarly, on September 8, 2020, Soriot signed a "pledge" together with eight other biopharmaceutical CEOs, in which he and AZN vowed that their Covid vaccine development would adhere to the highest manufacturing and clinical standards, "uphold the integrity of the scientific process," and submit a potential vaccine for EUA approval[6] only after demonstrating safety and efficacy through use of a single Phase III clinical study. ¶63.

**E. The Truth Emerged in a Series of Partial Revelations**

The truth began to emerge on November 23, 2020, when AZN announced the results of the Phase II/III trials for AZD1222. AZN first revealed to investors the existence of the dosing disparities and its switch to an LD/SD regimen in one of the cohorts. Counterintuitively, AZN claimed that the half-dosing regimen was substantially more effective at preventing Covid at 90% efficacy than the full-dosing regimen, which achieved just 62% efficacy. ¶78. AZN highlighted the blended "average efficacy of 70%" among the two trials, involving a total of 11,636 subjects. *Id.*

But while making this claim about 90% efficacy, Defendants omitted the critical fact that the half dose was not tested on older patients, so the vaccine was not 90% effective in that patient population. *See, e.g.*, ¶¶82, 89, 93-94, 112. This fact was revealed the next day, when the head of

[5] On August 31, 2020, AZN issued a press release announcing that it was expanding U.S. clinical trials for AZD1222 into Phase III while reiterating its commitment to the "highest safety standards," and stating, in relevant part: "[AZN] is today issuing a commitment to the highest safety standards and to broad and equitable access," reiterating its core values to "'follow the science' and 'put patients first.'" ¶61.

[6] Defendants argue that AZN never suggested that its vaccine would be approved for commercial use. *See* MTD at 2, 24-25. But Defendants misconstrue Plaintiffs' allegations – any references in the AC to the commercial sale or use of the vaccine are intended to mean EUA. *See, e.g.*, ¶¶6, 48, 56, 58, 62, 64, 68, 71, 77.

Operation Warp Speed, Dr. Moncef Slaoui, told reporters that AZN's half-strength dose had not initially been tested in people over the age of 55, raising the question of why AZN itself had not disclosed that important caveat about this population that was the most vulnerable to Covid. ¶82. Dr. Slaoui also stated that if AZN could not clearly explain the discrepancies in its trial results, the results would most likely "not be sufficient for approval" for commercial sale in the U.S. *Id*.

Although Defendants claim that the vaccine was efficacious and safe, *see* MTD at 1-2, analysts and reporters assailed the trial errors and AZN's lack of candor, describing AZN's interim results as a "mess," riddled with "irregularities and omissions," and the product of "cherry-picked . . . data" and "very shaky science" (¶83), and "controvers[ial] as some trial participants accidentally received a halved first dose of the vaccine . . . [and], the company did not test the half-strength first dose in older participants" (¶89). As one analyst noted:

> ***[T]he fact that the halved-first-dose regimen came about by accident rather than design has cast doubt over the reliability of the efficacy data***, and will likely ***complicate the company's request to regulators for emergency use authorization***. Further complicating matters, ***AZN announced that the initial half-strength dose wasn't tested in older participants (over 55)***, who are especially vulnerable to COVID-19. By contrast, the Pfizer/BioNTech and Moderna vaccines were both tested in older patients. Given these issues, and the fact that both the Pfizer and Moderna vaccines have shown more than 90% efficacy, we believe that AstraZeneca faces a high bar for authorization. ¶89.

Another analyst noted:

> ***We believe that this product will never be licensed in the US. This belief is based on the design of the company's pivotal trials (which does not appear to match the FDA's requirements for representation of minorities, severe cases, previously infected individuals and elderly and other increase risk populations)***, and based on the occurrence of severe safety events (why take the risk) that resulted in the extended clinical hold on enrollment into the trials in the US. ¶86.[7]

On November 25, 2020, *Wired* published a comprehensive report on AZN's botched trial results by Hilda Bastian, PhD, a health consumer advocate, entitled "The AstraZeneca Covid

[7] In a November 24, 2020 article, the same analyst, Geoffrey Porges of SVB Leerink, commented that, "I don't believe that the FDA will look positively at any trial where the dose, or the age cohorts, or any other variable were changed mid-trial, inadvertently or deliberately," and predicted that the FDA would not clear the vaccine. Walsh Decl. Ex. B.

Vaccine Data Isn't Up to Snuff." ¶83. Dr. Bastian criticized AZN for: (i) changing its protocol mid-trial, and testing a hypothesis that neither study was designed to test, further jeopardizing potential approval; (ii) including relatively few participants over the age of 55, even though that group is especially vulnerable to Covid; and (iii) combining the results of two studies to indicate strong test results, after AZN had made a pledge to adhere to a single Phase III study. *Id.*; *see also* ¶98. As negative news reports continued to reveal previously undisclosed problems in AZN's vaccine trials, the price of AZN ADSs fell from $55.30 on November 20, 2020, to close at $52.60 on November 25, 2020, a 5% decline in response to developing adverse news, on abnormally high volume. ¶92.

On December 8, 2020, the British medical journal *The Lancet* published the full data from the Phase II/III trials, resulting in more excoriation for AZN and its vaccine. For example:

- An SVB Leerink analyst commented that "the publication highlights a number of variances in the dosing regimens utilized in these trials that could make it difficult for the regulatory agencies to have confidence in the optimum dosing protocol for full approval without additional studies. The publication highlights the need for additional data to determine whether the LD/SD protocol is truly superior to the SD/SD protocol, given the number of imbalances in the arms of the existing trials." ¶109.
- Dr. Simon Clarke, an associate professor in cellular microbiology at the University of Reading, said the findings present "regulators with something of a dilemma." ¶111.
- *Reuters* and *Postmedia Breaking News* published articles entitled, "Testing times: More work needed on Astra/Oxford vaccine trials[,]" explaining how *The Lancet* article underscored just how far AZN's vaccine was from achieving clinical success. ¶112.
- The *National Post* reported that Dr. Larry Corey, a co-leader of the U.S. Coronavirus Vaccine Prevention Network who helped design and is overseeing trials for Operation Warp Speed, said that the dosing in the AZN-Oxford UK trial "wasn't done correctly. . . . One of the issues with the Oxford data is that there's a lack of uniformity in the schedule and the dose that makes interpretation of the results difficult at best[.]" Further, Dr. Corey believed that should AZN decide to run a new U.S. trial testing the LD/SD option, the U.S. was unlikely to help foot the bill. ¶113.

On December 14, 2020, AZN's ADSs fell again, this time by approximately 8%, when the *Daily Mail* published an article headlined "AstraZeneca 'would have done the study differently' if it had been in charge of Oxford's coronavirus vaccine, boss admits as UK regulator mulls over how to

use jab after confusing trial found it could be 62% or 90% effective[.]" ¶114. The article quoted Pangalos regarding the AZD1222 trial, stating: "There is no doubt I think that we would have run the study a little bit differently if we had been doing it from scratch," noting that AZN "was not part of the team that invented the vaccine . . . meaning it did not help design the first trials." *Id.* According to the *Daily Mail*, "Dr. Pangalos may have been suggesting the pharmaceutical giant would have run a trial where participants only received one dosing type, instead of two." *Id.*

On December 30, 2020, UK regulators announced the emergency approval for AstraZeneca's Covid vaccine. ¶115. The authorization recommended two full doses, but rejected use of the half-dose regimen AZN had highlighted as more effective, saying the data did not support the finding. *Id.* According to Munir Pirmohamed, the chair of the UK's commission for Covid vaccines, "[t]he low dose/standard dose regimen, although it has been quoted to have an efficacy of 90%, this is confounded by the fact that the interval between the first and second dose was quite long[.] And we feel that that result may be related to that interval, rather than the dose itself." *Id.*

The truth continued to be revealed, and the risks that had been previously concealed by Defendants continued to materialize, in early 2021. On January 26, 2021, newspapers quoted sources in the German government as saying the AZN vaccine was less than 10% effective in people over 65 years. ¶118. The papers said German officials now fear the EU's medicine regulator may not approve giving the AZN vaccine to such people. *Id.* Although AZN and Germany's health ministry rejected this assertion, on January 28, 2021, Germany's vaccine commission advised against using AZN's vaccine on older people. ¶119. In addition, the STIKO at Germany's disease-control agency found there was insufficient data on the effectiveness of the AZN vaccine for this age group "[d]ue to the small number of study participants in the age group ≥65 years," and refused to recommend AZN's vaccine for people over 64 years of age. *Id.* "This vaccine is therefore currently

recommended by STIKO only for persons aged 18-64 years." *Id.*

Then, on January 29, 2021, the CHMP issued an Assessment Report on the vaccine. The CHMP recommended AZN's Covid vaccine for approval in patients over 18, but noted that "[e]fficacy could not be demonstrated in subjects older than 55 . . . due to the low number of COVID-19 cases in this age group." ¶120. CHMP noted an efficacy level of 60%, which means the cohort in the trial that mistakenly received the wrong (half) dose was excluded from the data. *Id.*

In response to these additional damaging revelations, the price of AZN ADSs declined another 7% during the period of January 26 through January 29, 2021. ¶123.

**ARGUMENT**

To survive a motion to dismiss pursuant to Rule 12(b)(6), a plaintiff need only allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim has facial plausibility "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Courts must also "accept[] the complaint's factual allegations as true and draw[] all reasonable inferences in . . . plaintiff's favor." *Steginsky v. Xcelera Inc.*, 741 F.3d 365, 368 (2d Cir. 2014).

To state a Section 10(b) and Rule 10b-5 claim, a plaintiff must allege the following elements: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37-38 (2011).[8] To state a Section 20(a) claim, "a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was . . . a culpable participant in the controlled person's fraud."

[8] Here, Defendants challenge falsity, scienter, and loss causation. *See* MTD at 15-34.

*ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 108 (2d Cir. 2007).

## I. THE AC ADEQUATELY ALLEGES MATERIAL MISSTATEMENTS AND OMISSIONS

Plaintiffs have adequately alleged the falsity of Defendants' statements and material omissions. Under the PSLRA, a complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . state with particularity all facts on which that belief is formed." 15 U.S.C. §78u-4(b)(1). Plaintiffs need not plead "detailed evidentiary matter," *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 72 (2d Cir. 2001), but merely sufficient facts "to support a reasonable belief" that defendants' statements were materially false or misleading. *Novak v. Kasaks*, 216 F.3d 300, 314 n.1 (2d Cir. 2000); *see also City of Pontiac Gen. Emps.' Ret. Sys. v. Lockheed Martin Corp.*, 875 F. Supp. 2d 359, 367 (S.D.N.Y. 2012) (applying a plausibility standard to plead falsity). The issue of whether a statement is misleading is "evaluated not only by 'literal truth,' but by 'context and manner of presentation.'" *Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019). "At the motion to dismiss stage of a securities fraud action, the court reads ambiguities in challenged statements in [the plaintiff's] favor." *Skiadas v. Acer Therapeutics Inc.*, 2020 WL 3268495, at *9 (S.D.N.Y. June 16, 2020).

"A statement or omission is material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to act." *IBEW Loc. Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scot. Grp., PLC*, 783 F. 3d 383, 389 (2d Cir. 2015). The issue of materiality "is generally inappropriate for determination at the pleading stage." *In re Warnaco Grp., Inc. Sec. Litig. (II)*, 388 F. Supp. 2d 307, 313 (S.D.N.Y. 2005).

### A. Defendants Made Material Misstatements and Omissions

Consistent with the PSLRA and Rule 9(b), the AC identifies each misleading statement and

who made the statement, and explains in detail why it was misleading. *See* ¶¶44-77; *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 321 (2007). Specifically, the AC alleges that Defendants issued positive statements during the Class Period regarding the status and results of their vaccine's trials, the progress of its development, and testing of the vaccine on patients 55 and over, but failed to disclose that: (i) the trial experienced a manufacturing error that resulted in a protocol change involving an LD/SD regimen; (ii) the LD/SD regimen was not tested on anyone over 55; and (iii) the SD/SD regimen, as well as the trials overall, did not include a sufficient number of 55+ subjects to test the vaccine's efficacy in that population. *See supra* at 7.[9]

Defendants claim they had no duty to disclose these material facts (*see* MTD at 17-18), but they are wrong. It is "well-established precedent in this Circuit" that:

> [O]nce a company speaks on an issue or topic, there is a duty to tell the whole truth, [e]ven when there is no existing independent duty to disclose information on the issue or topic. . . . That is because, at the moment the company chooses to speak, it takes upon itself the obligation to ***speak truthfully***, and it is the breach of ***that*** obligation which forms the basis for the §10(b) claim.

*In re Vivendi Sec. Litig.*, 838 F.3d 223, 258 (2d Cir. 2016) (emphasis in original); *In re Kirkland Lake Gold Ltd. Sec. Litig.*, 2021 WL 4482151, at *2 (S.D.N.Y. Sept. 30, 2021) (Oetken, J.) (same).

Here, Defendants' statements created the misleading impression that their trials were

[9] Defendants claim that the AC "engages in a puzzle-pleading approach that block quotes extensively . . . and then repeats the same set of assorted purported omissions," and thus fails to sufficiently identify the challenged misstatements and omissions. MTD at 16 n.13. The AC, however, identifies the false and/or misleading portion of block quotes, and other quotes, by bolding and italicizing when necessary, which is sufficient. *See, e.g.*, *In re NTL, Inc. Sec. Litig.*, 347 F. Supp. 2d 15, 22 (S.D.N.Y. 2004) (declining to dismiss a complaint that alleged less than the AC, including when portions of long quotes were not identified as misleading, because plaintiffs identified the date, source, speaker, and why the statements were misleading). Furthermore, this argument ignores the AC's allegations that specifically pinpoint which portions of Defendants' statements were misleading and why. *See, e.g.*, ¶48 ("The statements referenced in ¶¶44 and 47 above, ***regarding the positive interim results and tests being underway in different age ranges***, were materially false and/or misleading when made[.]"). Defendants' reliance on *Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App'x 32, 36 (2d Cir. 2012), and *In re Alcatel Securities Litigation*, 382 F. Supp. 2d 513, 534 (S.D.N.Y. 2005) (MTD at 16 n.13), is misplaced. "Courts have found . . . that a complaint meets the particularity requirement when" – as here – "it specifically identif[ies] the date, publication, and speaker of each of the alleged misstatements or omissions and contain[s] facts supporting the existence and materiality of these problems and highlights in some way the particular aspects of the statements alleged to be misleading." *Ont. Tchrs.' Pension Plan Bd. v. Teva Pharm. Indus. Ltd.*, 432 F. Supp. 3d 131, 153 (D. Conn. 2019). "The []AC is thus not a complaint that is so [v]ague and disorganized as to fail to satisfy Rule 9(b) and the PSLRA." *In re MF Glob. Holdings Ltd. Sec. Litig.*, 982 F. Supp. 2d 277, 309 (S.D.N.Y. 2013) (alteration in original).

proceeding as expected, producing positive results, and assessing efficacy in 55+ subjects, with no significant setbacks or unusual issues. But "the undisclosed reality was materially different." *Kendall v. Odonate Therapeutics, Inc.*, 2021 WL 3406271, at *5 (S.D. Cal. Aug. 4, 2021). Thus, Plaintiffs have "sufficiently alleged that the omitted information" may have "rendered Defendants' public statements misleading." *Id*. at *6; *see also In re Delcath Sys., Inc. Sec. Litig*., 36 F. Supp. 3d 320, 333 (S.D.N.Y. 2014) (defendants' statements of positive trial results "were misleading without the disclosure of additional facts that would cast those results in a more negative light"). Defendants' argument that their statements were true (MTD at 17-19) is unpersuasive because "even an entirely truthful statement may provide a basis for liability." *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 561 (S.D.N.Y. 2011); *see also McMahan v. Wherehouse Entm't, Inc.*, 900 F.2d 576, 579 (2d Cir. 1990) ("the disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers").

The decision in *Odonate* is directly on point. There, plaintiffs alleged that defendants misled investors by making positive statements about their drug trial results, while failing to disclose that they had been forced to make an emergency protocol change because their drug had caused side effects that made patients drop out of the studies. *Odonate*, 2021 WL 3406271, at *3. The court found that "once Defendants chose to speak on certain topics," such as the completion of enrollment in their drug trials or the "top-line" results they produced, "they were bound to do so in a manner that wouldn't mislead investors." *Id.* at *6. This rule applied notwithstanding that the defendants' statements regarding top line results were "literally true."[10] *Id.*; *see also In re Allergan PLC Sec.*

[10] *Odonate* also refutes Defendants' argument that "there is no duty to disclose such granular information about supposed clinical trial 'miscues' as execution continues." MTD at 22. There, the court found that "[d]efendants allegedly did not disclose the adjustment to the trial protocol at any point during [the trial], nor during the reporting and discussion of [the trial's] top-line results; it is plausible that a reasonable investor would find the omission misleading." *Odonate*, 2021 WL 3406271, at *6. The court found that it could not "determine at this time – as a matter of law – that the omitted information did not make the statements made by Defendants during the Class Period misleading to a reasonable investor." *Id*. Here, Plaintiffs have similarly alleged a protocol change made by AZN, which was disclosed

*Litig.*, 2019 WL 4686445, at *23 (S.D.N.Y. Sept. 20, 2019) ("even a statement that is literally true when viewed in isolation can be misleading in context if it leaves investors with a false impression").

Here, it is plausible that a reasonable investor would have considered the omitted information concerning the dosing error,[11] protocol change, and lack of testing on the 55+ population as material, given that: (i) the trials were not designed to test the differences in efficacy of the LD/SD regimen versus the SD/SD regimen, and that such a change in protocol may affect the granting of EUA (¶86); and (ii) insufficient testing of the age population most vulnerable to severe Covid, such that vaccine efficacy could not be assessed, completely undermined the reliability of the studies as to the effectiveness of the AZN vaccine for that critical demographic. ¶¶82-83, 86, 89.

Defendants' argument that they did not specify or promise they would test the vaccine on any specific number of older patients fails. *See* MTD at 18, 20. Although Defendants stated that "a small number" of older adults were included in their trials, they nevertheless created the misleading impression that the number of 55+ subjects was sufficient to be studied, which was not true.

to regulators but not investors (¶42), and when it was eventually disclosed to investors, caused concerns because the trial was not meant to test a different dosing hypothesis (¶83), and raised questions about its ultimate likelihood to receive EUA (¶¶85-86, 90). Plaintiffs have also alleged that the LD/SD regimen was never tested on the 55+ population, and the SD/SD regimen was not tested on a sufficient number of 55+ subjects to be studied. ¶¶82, 105, 120. Based on these materially misleading statements and omissions, as opposed to a critique of the trial design or methodology, many of the cases that Defendants rely on (MTD at 23 n.22) are distinguishable. *See, e.g., In re Keryx Biopharm., Inc. Sec. Litig.*, 2014 WL 585658, at *11 (S.D.N.Y. Feb. 14, 2014) ("plaintiffs assert that the methodology suffered"); *In re Philip Morris Int'l Inc. Sec. Litig.*, 2021 WL 4135059, at *10 (S.D.N.Y. Sept. 10, 2021) ("Plaintiffs challenge the wisdom of these studies' methodologies"); *In re Neurotrope, Inc. Sec. Litig.*, 315 F. Supp. 3d 721, 732 (S.D.N.Y. 2018) (plaintiffs "alleged [an] omission of the statistical methodology"). Other of the cases, including *Lehmann v. Ohr Pharmaceutical Inc.*, 2019 WL 4572765 (S.D.N.Y. Sept. 20, 2019), *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557 (S.D.N.Y. 2016), and *In re MELA Sciences Securities Litigation*, 2012 WL 4466604 (S.D.N.Y. Sept. 19, 2012), are distinguishable because there, the plaintiffs were complaining that defendants failed to provide specifically desired study results – as opposed to here, where Plaintiffs allege Defendants' omissions rendered other statements they made false and misleading.

[11] Defendants assert that the "manufacturing error" was instead a difference in manufacturing technique used by a third-party manufacturer. MTD at 22. But this raises an issue of fact, inappropriate for determination at the motion to dismiss stage. *Speakes v. Taro Pharm. Indus.*, 2018 U.S. Dist. LEXIS 163281, at *16 (S.D.N.Y. Sept. 24, 2018). Defendants also argue that they never promised that a single-dosing regimen would be used in the Phase II/III trial, and, to the contrary, AZN disclosed that the vaccine would be tested "at various doses." MTD at 22. But Defendants did not need to promise anything about a single-dosing regimen. Once they spoke about the status of that trial, they had a duty to disclose this error. *See supra* at 5-8, 14. Indeed, the cohort that resulted from the error was touted by Defendants at 90% efficacy, but ultimately was abandoned because the data did not support the finding. ¶¶78, 115.

*Compare* ¶¶47, 50 (Phase II/III trials are currently underway "in different age ranges"); ¶70 ("It is encouraging to see immunogenicity responses were similar between older and younger adults and that reactogenicity was lower in older adults, where the COVID-19 disease severity is higher[.]"); *with* ¶105 (quoting December 8, 2020 *Lancet* article: "Vaccine efficacy in older age groups could not be assessed but will be determined, if sufficient data are available, in a future analysis after more cases have accrued."); ¶120 ("[e]fficacy could not be demonstrated in subjects older than 55 . . . due to the low number of COVID-19 cases in this age group"). For instance, in response to an analyst asking for "comment to give us timing at all when you may have some data on elderly [patients]," Pangalos stated that "***data on different age groups*** is coming from the Phase I study and from the Phase II part and the Phase III study we're running in the U.K., and we're getting that data in on a weekly basis." ¶54. And Pangalos made this statement on July 30, 2020, even though AZN did not even begin enrolling older patients in the Phase II/III trials until August 8, 2020. ¶103.

Moreover, in their November 5, 2020 statements, Defendants repeatedly emphasized the supposedly strong immunoresponse in the older population, a statement that was clearly designed to make investors believe the vaccine was effective in older adults. *See* ¶76 ("the immune response in the 56 to 69 year olds and 69 and 70 and above looks very similar to the response of the 18 to 55 year olds"). Less than three weeks later, however, AZN announced that the vaccine showed 90% effectiveness only in the LD/SD regimen, which had not been tested on 55+ subjects, meaning that the 90% effectiveness was unaffected by, and did not account for, that segment of the population. And the SD/SD regimen did not even include enough 55+ participants to measure efficacy. ¶¶119-120. Analysts and news outlets immediately highlighted the problem of not testing the vaccine on those 55 and older (*see, e.g.*, ¶¶82, 83, 86, 89),[12] underscoring the misleading nature of Defendants'

[12] Defendants' statement that "the immunogenicity data set came primarily from older adults" (MTD at 20 n.18) is misleading because it created the impression that the trials were able to assess efficacy in the 55+ population, even

November 5, 2020 statements.[13]

Defendants are also wrong in claiming that the AC is based on an inactionable challenge to AZN's trial design or interpretation of trial results. *See* MTD at 17-18, 23-25. Plaintiffs are not critiquing the trial design or results; rather, they are challenging the veracity of Defendants' statements regarding the trial design and results. For example, during a September 8, 2020 investor conference call, Soriot "expressed his confidence in the design of the trials, safety protocols and DSM."[14] ¶67. In addition, Soriot and AZN repeatedly emphasized their adherence to "the highest scientific and clinical standards" in their development of AZD1222. ¶60. Soriot claimed that AZN was developing AZD1222 "without cutting corners" and was following the "clear and stringent efficacy and safety standards" set by regulators. *Id*.; *see also* ¶61.

These statements were materially false and misleading because, in fact, the design of the trials was fundamentally flawed and AZN was not adhering to the highest scientific and clinical standards. Specifically, Defendants failed to disclose that: (i) the trials had suffered from a critical

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though the LD/SD regimen was never tested on the 55+ population, and the SD/SD regimen was not tested on a sufficient number of 55+ subjects to be studied. ¶¶82, 105, 120.

[13] Defendants assert that a November 19 *Lancet* publication released a few days before AZN's November 23, 2020 trial-results release had already "noted that low and standard dose regimens were used, and approval of the June 5 protocol amendment." MTD at 22 n.21. First, this supposed disclosure was unclear and ambiguous, as it did nothing more than tersely disclose that two regimens were used and approved. It certainly did not explain that there was a manufacturing error and how the two regimens came to be or how both Oxford and AZN sought the protocol amendment. ¶¶78-81; *see also* ¶88 (quoting November 23, 2020 analyst report: "While the company may have internal evidence to guide its half/full regimen, we were unable to find anything in the public domain that would have predicted this outcome for the half/full dose regimen."). In fact, one analyst, following the November 23, 2020 release, stated that, "AZN-LON did publish additional data ***with a low-low and high-high dose regimen in its recent Lancet publication but none incorporating a low-high dose regimen***." ¶88. Further, this is irrelevant to the falsity of the Class Period statements that were made weeks and months prior to the *Lancet* article.

[14] Defendants argue that "AZ demonstrated its commitment [to safety], when it announced that, per standard procedure, vaccination in all trials had been voluntarily paused to allow independent review of safety data from a single event of unexplained illness in COV002. Ex. 23. Mr. Soriot stated that '[t]his temporary pause is living proof' that 'we put science, safety and the interests of society at the heart of our work.' *Id.*" MTD at 8. This argument fails because, as the AC alleges, the story of the halted trial broke on September 8, which was actually how the FDA was informed of the stoppage. ¶65. And when the FDA's commissioner found out through the news (and not through AZN), he was "stunned." *Id*. Further, Soriot's statement at the JP Morgan Healthcare CEO conference did not reflect a public commitment to safety, *see* MTD at 8 n.3, but rather shows how AZN cynically viewed safety, because instead of releasing more information about the trial participant's illness ***publicly***, he provided new details to select investors on a ***private*** conference call. ¶66.

manufacturing error, resulting in a portion of participants receiving half the designed dose; (ii) the trials consisted of a patchwork of disparate patient subgroups, each with subtly different treatments, undermining the validity and import of the conclusions that could be drawn from the clinical data across these disparate patient populations; (iii) certain trial participants had not received a second dose at the designated time points, but rather received the second dose up to several weeks after the dose had been scheduled to be delivered according to the original trial design; (iv) AZN failed to include a sufficient number of patients over 55 years of age in the trials to assess efficacy, and no patients over 55 in the half-dose regimen, despite this patient population being particularly vulnerable to the effects of Covid; (v) the trials had been hamstrung by widespread flaws in design, errors in execution, and a failure to properly coordinate and communicate with regulatory authorities and the general public; and (vi) the trials failed to follow relevant and applicable protocols and guidelines, including, without limitation, the guidelines for Good Clinical Practice. *See, e.g.*, ¶¶62, 82-90. By making positive statements concerning the design of the trials, AZN's adherence to "the highest scientific and clinical standards," and affirming that it was following the "clear and stringent efficacy and safety standards," Defendants put AZN's conduct of the trials at issue. *See Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 250 (2d Cir. 2014) ("Even when there is no existing independent duty to disclose information, once a company speaks on an issue or topic, there is a duty to tell the whole truth."). Because Defendants knowingly or recklessly omitted material information about the trials, they are liable for those misstatements.[15]

[15] Defendants' argument that the alleged misstatements concerning AZN's commitment to the highest safety, science, and clinical standards are inactionable similarly fails. *See* MTD at 21 & n.19. The cases cited by Defendants for this proposition are not comparable to the facts in this case given the unique context surrounding the effort to develop an effective and safe vaccine to combat the global Covid pandemic. *See Matrixx Initiatives*, 563 U.S. at 44 ("contextual inquiry" required to assess materiality). Instead, the statements alleged in the cited cases revolved around code of conduct or ethical issues. *See In re AT&T/DirecTV Now Sec. Litig.*, 480 F. Supp. 3d 507, 523-34 (S.D.N.Y. 2020) (company's statements touting its "'core set of values,' set forth in its 'Code of Business Conduct,' and its commitment to 'the highest standards' and 'operating with integrity, transparency, and honesty in everything' it does" were puffery); *In re MGT Cap. Invs., Inc. Sec. Litig.*, 2018 WL 1224945, at *13 (S.D.N.Y. Feb. 27, 2018) (company's commitment to "the highest standards of transparency and corporate governance" was inactionable puffery); *Barrett v. PJT Partners*

Further, *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 153-55 (2d Cir. 2013), is inapposite. *See* MTD at 18-19. In *Kleinman*, unlike here, "the defendant . . . disclosed the negative data at issue, and then attempted to explain it away by applying statistical analysis the plaintiff believed was misleading." *Delcath*, 36 F. Supp. 3d at 333 (discussing *Kleinman*). "The allegations here," as in *Delcath*, "do not involve differing interpretations of disclosed data, but rather data [and other information] that was not disclosed." *Id.* Because Plaintiffs are not challenging the trial design per se, or arguing that Defendants' improperly withheld trial results – but are instead arguing that Defendants' omissions rendered certain statements false and misleading, *see supra* at 13-18 – the cases relied on by Defendants are distinguishable. *See Tongue v. Sanofi*, 816 F.3d 199, 210 (2d Cir. 2016) (challenges to testing methodologies); *Philip Morris*, 2021 WL 4135059, at *9-*10 (challenges to defendants' subjective interpretation of clinical trial data and to the trials' methodologies); *Abely v. Aeterna Zentaris Inc.*, 2013 WL 2399869, at *7 (S.D.N.Y. May 29, 2013) (challenges to trial methodology); *Davison v. Ventrus Biosciences, Inc.*, 2014 WL 1805242, at *7 (S.D.N.Y. May 5, 2014) (same); *Keryx*, 2014 WL 585658, at *10 (same).[16] Indeed, "a court does

*Inc.*, 2017 WL 3995606, at *6 (S.D.N.Y. Sept. 8, 2017) (company's statements regarding commitment to "the highest ethical standards" found within the code of conduct were inactionable). Here, where the development of a safe and effective vaccine on a dramatically expedited timeline was critically important, the alleged misstatements regarding adherence to safety, scientific, and clinical standards cannot be considered mere puffery. *See In re BHP Billiton Ltd. Sec. Litig.*, 276 F. Supp. 3d 65, 80 (S.D.N.Y. 2017) ("We also note that safety was obviously a major concern to BHP and investors, as indicated by defendants' extensive, frequent, and prominent discussions of the topic in their disclosures to investors . . . over and over and over."). Additionally, the rapid nature of the effort to develop a Covid vaccine within a year – when the process typically takes 15-16 years (¶23) – contributed to the public's vaccine hesitancy and skepticism, and in that context, it was critically important for the public to know that AZN's vaccine trials were being conducted in accordance with the highest safety standards. *See* ¶¶27-28, 69. Thus, unlike in the aforementioned cases, Defendants here were trying to induce the market to rely on their statements. *See Casella v. Webb*, 883 F.2d 805, 808 (9th Cir. 1989) ("What might be innocuous 'puffery' or mere statement of opinion standing alone may be actionable as an integral part of a representation of material fact when used to emphasize and induce reliance upon such a representation."). Defendants' reliance on *In re Philip Morris International Inc. Securities Litigation*, 437 F. Supp. 3d 329, 350 (S.D.N.Y. 2020), for this same proposition is similarly unpersuasive. *See* MTD at 21 n.19. The court found that statements regarding "extensive and rigorous scientific studies" could not amount to a guarantee regarding the ***quality*** of Philip Morris's studies or the likelihood of ***approval*** and were therefore deemed puffery. *Philip Morris*, 437 F. Supp. 3d at 350. That is unlike the case at hand where the challenged statements do not concern the quality of the trials or approval per se, but rather, Defendants' statements and omissions surrounding the dosing error and testing on particular age groups put their trial design and execution at issue.

[16] Defendants' other cited authorities attacking the falsity of trial results, status, and testing are similarly distinguishable

not judge the methodology of a drug trial, but whether a defendant's statements about that study were false and misleading." *Abely*, 2013 WL 2399869, at *7 (citing *Kleinman*, 706 F.3d at 154-55).

**B. The Alleged Misstatements Are Not Puffery or Inactionable Opinions**

Defendants claim that the statement "[t]he study remains on track" and statements about progress concerning vaccine development are puffery. MTD at 19 n.16, 25. "Puffery is an optimistic statement that is so vague, broad, and non-specific that a reasonable investor would not rely on it, thereby rendering it immaterial as a matter of law." *In re Vivendi Universal, S.A. Sec. Litig.*, 765 F. Supp. 2d 512, 572 (S.D.N.Y. 2011). A statement is immaterial as a matter of law, however, only when it is "so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of [its] importance." *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 162 (2d Cir. 2000). "[C]ourts will not insulate relatively general positive statements from liability if they are 'misrepresentations of existing facts.'" *Hawaii Structural Ironworkers Pension Tr. Fund v. AMC Ent. Holdings, Inc.*, 422 F. Supp. 3d 821, 845 (S.D.N.Y. 2019). And determining whether a statement is actionable "always depends on context." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 190 (2015).[17]

Here, the statement that the studies were "on track" was materially misleading given

and do not support dismissal. For instance, the cases at MTD at 19 n.17 deal with "Defendants' subjective interpretation of clinical trial data," which Plaintiffs are not challenging. The cases at MTD at 21 n.19 are distinguishable in that they deal with quality guarantees regarding clinical trials, whereas here, Plaintiffs are not challenging general quality guarantees. And the cases at MTD at 25 n.24 are distinguishable in that they deal with statements regarding a defendant's general "confidence," which Plaintiffs are not challenging. Rather, as discussed above, *supra* at 13-18, Plaintiffs allege that Defendants' omissions rendered misleading other statements they made regarding the trials.

[17] The cases that Defendants rely on are distinguishable. *See* MTD at 19-20. Defendants rely on *Tongue*, 816 F.3d at 210, to argue that their "subjective interpretation of clinical trial data are opinions" and Plaintiffs must, but fail to, allege that Defendants' interpretation was irrational or unreasonable. MTD at 19. Not so. *Tongue* does not stand for the sweeping proposition that Defendants' statements regarding trial results are all opinions, *see id.*, and many statements here are statements of verifiable fact. *See supra* at 5-8. It merely stands for the unremarkable proposition that the statements made by the defendants in that case about clinical trial results "were not misleading simply because the FDA disagreed with Defendants' interpretation of the data; an issuer is not liable merely because it knows, but fails to disclose, some fact cutting the other way." 816 F.3d at 214 (quoting *Omnicare*, 575 U.S. at 189-90). Here, the AC alleges facts "showing a conflict between Defendants' statements" and facts known to or recklessly disregarded by Defendants undermining the accuracy of Defendants' statements – including the protocol change and that AZN's half-strength dose had not been tested in people over the age of 55, and the full-strength dose had not been tested on sufficient subjects 55 and over to access efficacy. *Id.*; *see also* ¶82.

Defendants' omission of the dosing error and the need to change the protocol, which may have (and, in actuality, did) impact the vaccine's ability to obtain EUA – something that was clearly important to shareholders. In this context, the challenged statements are actionable. *See, e.g.*, *Odonate*, 2021 WL 3406271, at *5 (finding defendants' statements, including that they were "to complete enrollment of [a Phase 3 study] in the second half of 2019" and referring to the studied drug's potential as "generally well-tolerated" by patients having a "favorable benefit-risk profile," "created an impression that [the study] was proceeding as expected, with no significant setbacks – especially none that would potentially undermine the central rationale behind the trial – while the undisclosed reality was materially different"); *Delcath*, 36 F. Supp. 3d at 331-33 (finding defendants' literally true disclosures about Phase III trial results misleading "because the Complaint alleges that insufficient facts were disclosed to allow a reasonable investor to make an accurate assessment of the disclosures that were made"); *Iowa Pub. Emps.' Ret. Sys. v. MF Glob., Ltd.*, 620 F.3d 137, 144 (2d Cir. 2010) (finding actionable "characterizations of MF Global's risk-management system" as "robust"); *Novak*, 216 F.3d at 315 ("state[ments] that the inventory situation was 'in good shape' or 'under control' . . . were plainly false and misleading").

Moreover, when statements are "made repeatedly in an effort to reassure the investing public about matters particularly important to the company and investors, those statements may become material to investors." *BHP Billiton*, 276 F. Supp. 3d at 79 (collecting cases). Because Defendants repeatedly commented on the progress of the vaccine, these statements cannot be considered puffery.

Nor are the statements inactionable opinions. *See* MTD at 25-26. Defendants' representations regarding the age groups on whom the vaccine was tested and the status and progress of ongoing trials are not opinions at all – they are verifiable statements of fact. *See Abramson v. NewLink Genetics Corp.*, 965 F.3d 165, 176 (2d Cir. 2020) (statement was not an opinion given

"specificity of the representation and the authority with which it was made").[18]

Even assuming, *arguendo*, any alleged misrepresentations are considered opinions, the AC alleges facts that satisfy the test for pleading opinion liability. Under *Omnicare*, a statement of opinion is actionable if it: (i) is not sincerely held by the speaker (575 U.S. at 184); (ii) contains an embedded or "underlying" fact that is false (*id.* at 185-86); or (iii) omits a fact that renders it misleading to an ordinary investor (*id.* at 189-90). The AC satisfies the third prong because Defendants failed to disclose that: (i) the Phase II/III trials suffered from a critical manufacturing error; (ii) the manufacturing error necessitated the creation of an LD/SD cohort that the trials had not been designed to test, and that required a formal change in trial protocol; and (iii) AZN had failed to include a sufficient number of patients over 55 years of age in the trials to assess efficacy. *See* ¶¶78-123; *see also In re iDreamSky Tech. Sec. Litig.*, 236 F. Supp. 3d 824, 833 (S.D.N.Y. 2017) (Oetken, J.) ("[O]pinions, though sincerely held and otherwise true as a matter of fact, may nonetheless be actionable if the speaker omits information whose omission makes the statement misleading to a reasonable investor" and holding that "[t]he failure to acknowledge the then-known delays in the launch of Cookie Run and to update the 2014 revenue projections accordingly is precisely the type of omission that, even if included in the context of an opinion, would be misleading to a reasonable investor"). By asserting that their vaccine produced strong immune responses in older test subjects, Defendants represented that they had a factual basis for their statements, which they lacked because the trial included an insufficient number of 55+ patients to assess efficacy.[19] *See Omnicare*, 575 U.S. at 188 ("[A] reasonable investor may . . . understand an

[18] The majority of the misstatements alleged in the AC are also statements of fact, because, as the Supreme Court observed in *Omnicare*, investors recognize opinions by the presence of certain signals – expressions such as "I believe" or "I think" – which are missing here. 575 U.S. at 187.

[19] Similarly unpersuasive is Defendants' argument that the statements surrounding the trial results are opinions. MTD at 19-20. The AC does not allege misstatements of opinions surrounding the trial, but, instead, alleges that Defendants misleadingly described the clinical trial (*i.e.*, issues in the LD/SD regimen). *See Shanawaz v. Intellipharmaceutics Int'l Inc.*, 348 F. Supp. 3d 313, 324-25 (S.D.N.Y. 2018) (Oetken, J.) ("At issue here are not Defendants' opinions about the

opinion statement to convey facts about how the speaker has formed the opinion – or, otherwise put, about the speaker's basis for holding that view. And if the real facts are otherwise, but not provided, the opinion statement will mislead its audience."); *Tongue*, 816 F.3d at 214 (issuer must have "conducted a meaningful inquiry and ha[ve] a reasonable basis upon which to make such an assertion").

Defendants' reliance on *Philip Morris* is misplaced because there, unlike here, the court found that the complaint "ma[de] clear that Defendants had a reasonable basis for making the [challenged] statements of opinion." 2021 WL 4135059, at *10. Moreover, there the court found the fact that the FDA "essentially endorsed Defendants' statements about its scientific data, even after considering the studies that Plaintiffs characterize as contradictory, severely undercut[] any allegation that the statements were false or misleading when made." *Id.* Here, however, Defendants' statements have not been endorsed by the FDA, and other experts have questioned or challenged the accuracy of Defendants' statements, including the head of Operation Warp Speed. ¶¶82-91.[20] Moreover, there, unlike here, the court found it "[wa]s apparent from the Complaint . . . that Defendants' statements constituted reasonable interpretations of the available data and were not substantially undermined by omitted facts[.]" *Philip Morris*, 2021 WL 4135059, at *13. For these reasons, the cases that Defendants rely on to attack certain of the challenged statements as

NDA's prospects before the FDA, but Defendants' allegedly false descriptions of the contents of the NDA itself.").

[20] Defendants, in response, will likely highlight that the AZN vaccine has been approved and is currently in use in numerous countries around the world. *See, e.g.*, MTD at 1, 14. First, the Court should not consider these extraneous materials. *See infra* at 37. Second, such approval and use does not excuse Defendants' obligation to disclose material facts. Third, it is indisputable that: (i) the FDA has still not approved the AZN vaccine (Walsh Decl. Ex. A); and (ii) the AZN vaccine was widely criticized following the release of the Phase II/III results (¶¶82-91, 95-99, 106-113, 116-118, 120-122). Further, the AZN vaccine has not inspired the same public confidence or use as the Moderna and Pfizer vaccines. As the *Daily Mail* noted, the 90% efficacy of the LD/SD cohort was being challenged by experts because of the small number of people it was tested on. Only 2,300 volunteers were given the smaller dose and none of the volunteers were over 55, the most high-risk age group for Covid. By contrast, in the Moderna and Pfizer vaccine trials, which are about 95% effective, dosing regimens were tested on 30,000 volunteers and more than 40% of those volunteers were over 55. ¶96; *see also* ¶83 ("So here we are at the end of November [2020]. BNT-Pfizer and Moderna have offered up a masterclass in how to do major vaccine trials quickly in a pandemic, while Oxford-AstraZeneca has, for the moment, only an assortment of smaller ones ready to look at.").

inactionable puffery/statements of corporate optimism and opinions (*see* MTD at 25-26) are inapposite and distinguishable.[21]

### C. Defendants' Risk Warnings Do Not Shield Them from Liability

Defendants' safe-harbor arguments are limited to only certain of the challenged misstatements – that is, those "concerning the clinical trial activity planned; the clinical trial data, what it would ultimately show, and how it would be used for regulatory submissions; standards to be followed for future regulatory submissions; and potential for regulatory approvals, *see* ¶¶ 47, 49, 50, 53, 54, 57, 60, 70, 72, 74, 75" (MTD at 26).[22] These misstatements are not insulated from liability.[23]

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[21] Defendants' cited cases also do not help them for other reasons. For instance, in *ECA & Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, the court merely declined to adopt a bright-line rule that statements relating to a bank's reputation are *per se* material, finding statements such as JP Morgan "set the standard for integrity" were "too general to cause a reasonable investor to rely upon them." 553 F.3d 187, 205-06 (2d Cir. 2009). Also, there, the court acknowledged that, given the fact-intensive nature of the materiality inquiry, a court may not dismiss a complaint "on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *Id.* at 197. This principle applies in full force here.

In addition, the statements and circumstances here differ from those in *In re Aratana Therapeutics Inc. Securities Litigation*, 315 F.Supp.3d 737, 757-58 (S.D.N.Y. 2018), *Nguyen v. New Link Genetics Corp.*, 297 F. Supp. 3d 472, 489 (S.D.N.Y. 2018), and Defendants' other cited cases, where there were no allegations of share price increases following the challenged statements and material share price decreases following the alleged revelations of the truth. *Cf. Ganino*, 228 F.3d at 166 (stock decline supports materiality). Further, in *Aratana*, the court merely found that defendants' statements, including that Aratana was "'confident about and prepared for what lays ahead[]'…[and] 'proud' to be 'on track to have these products reach the market in 2016,'….[did] no more than place a 'positive spin on developments in the [FDA approval] process.'" 315 F. Supp. 3d at 758; *see also In re Diebold Nixdorf, Inc., Sec. Litig.*, 2021 WL 1226627, at *10 & n.13 (S.D.N.Y. Mar. 30, 2021) ("Plaintiff's suggestion that the Company's Merger-related reporting [including statements expressing 'confidence' about merger integration] was all roses is divorced from its own pleadings and Defendants' other public statements."); *Nguyen*, 297 F. Supp. 3d at 489 (finding "nothing" misleading about statements that NewLink was "confident" in Phase 2's study design and "encouraged" before rejecting plaintiffs' argument "that NewLink improperly utilized Phase 2 data to extrapolate Phase 3's success, [given that] no reasonable investor would have credited that inference").

[22] Defendants do not challenge as forward-looking any portions of statements regarding: (i) the start of trials post-protocol change (¶¶44, 51, 52, 61); (ii) AZN's commitment to science and safety, and Soriot's pledge to only submit for EUA approval after demonstrating safety and efficacy through use of a single Phase III study (¶¶63, 67, 73); and (iii) the immune response of older patients (¶76). And they seemingly only challenge portions of the remaining statements.

[23] Defendants' cases cited for the proposition that the challenged statements are forward-looking also miss the mark. Those cases are inapposite because the AC does not criticize the way AZN designed the trials or their expectations regarding any type of approval, but rather challenges AZN's concealment of then-current facts surrounding the AZD1222 trial – *i.e.*, the dosing error and the lack of testing done on the 55+ population. *See* MTD at 26 & n.26; *Gillis*, 197 F. Supp. 3d at 591 (company's "statement that it was '*confident* that MOXDUO will *receive approval*,' [] is, separately, shielded by the PSLRA safe harbor. It is forward-looking and the SAC does not allege that it was 'made with actual knowledge . . . that [it was] false or misleading.'"); *Schaeffer v. Nabriva Therapeutics plc*, 2020 WL 7701463, at *10 (S.D.N.Y. Apr. 28, 2020) ("statements that Defendants *expected* CONTEPO to win FDA *approval* and intended to launch CONTEPO shortly after approval are both forward-looking"); *Aratana Therapeutics*, 315 F. Supp. 3d at 758

*First*, Defendants' affirmative misstatements regarding testing on 55+ participants were statements of purported current and/or historical fact, which are not, by their very nature, forward-looking. *See In re ITT Educ. Servs., Inc. Sec. Litig.*, 34 F. Supp. 3d 298, 306 (S.D.N.Y. 2014) (Oetken, J.) (safe harbor was not triggered when plaintiffs alleged that "at the time the statement was made, it was already untrue"); *iDreamSky*, 236 F. Supp. 3d at 833 (statements made by defendants were not shielded by the safe harbor since plaintiffs had adequately pleaded enough to suggest that defendants "were fully aware of the delays affecting the launch date of Cookie Run").

*Second*, to the extent the challenged misstatements are material omissions, they fall outside the safe harbor. *See, e.g., Galestan v. OneMain Holdings, Inc.*, 348 F. Supp. 3d 282, 304 (S.D.N.Y. 2018) ("courts in the Second Circuit have consistently held that the PSLRA safe harbor . . . [does not] protect[] material omissions"); *In re Salix Pharms., Ltd.*, 2016 WL 1629341, at *9 (S.D.N.Y. Apr. 22, 2016) (collecting cases). Thus, Defendants' omissions that: (i) the Phase II/III clinical trials suffered from a critical manufacturing error, necessitating the creation of an LD/SD cohort that the trials had not been designed to test; and (ii) AZN had failed to include a substantial number of 55+ patients in the Phase II/III clinical trials, lack safe harbor protection. *See, e.g.*, ¶¶78-123.[24]

*Third*, to the extent applicable, the purported risk warnings (MTD at 26-27; App'x B) fail to satisfy the PSLRA safe harbor, which protects statements identified as forward-looking and accompanied by meaningful cautionary language. *See* 15 U.S.C. §78u-5(c)(1)(A)(i). Defendants do

("Nearly all of defendants' statements as to their *expectations regarding FDA approval* and the timeline for ENTYCE's commercial release were framed as opinions, forward-looking statements, or both."); *Gregory v. ProNAi Therapeutics Inc.*, 297 F. Supp. 3d 372, 403-04 (S.D.N.Y. 2018) (finding statements regarding scientific viability of a drug containing words such as *could*, *believe*, and *may initiate* were forward-looking statements); *Fort Worth Emps.' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 230 (S.D.N.Y. 2009) (finding statements that reflected "the slightest degree of optimism" regarding FDA approval were forward looking).

[24] Similarly, Defendants' cited risk disclosures (MTD at 26-27) did not disclose, for example, that AZN had discovered the dosing error and had amended the study protocol on June 5, 2020. ¶¶42, 139. They also did not mention the then-current lack of sufficient testing on the critical 55+ population. ¶¶82, 105. These omissions further render false and misleading the statements regarding the clinical trial activity planned, the clinical trial data, the standards to be followed for future regulatory submissions, and potential for regulatory approvals, because they call into question the progress, data, and standards of the trial, as well as the potential for AZN to obtain EUA for the vaccine.

not demonstrate that the specified misstatements were identified as forward-looking, and they quote hedged, speculative, cautionary language, concerning events that had already occurred when they spoke. Such warnings are legally insufficient. *See Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1181 (9th Cir. 2009), *aff'd*, 563 U.S. 27 (2011) ("the Form 10-Q speaks about the risks of product liability claims in the abstract, with no indication that the risk 'may already have come to fruition'"); *In re Facebook, Inc., IPO Sec. & Derivative Litig.*, 986 F. Supp. 2d 487, 516 (S.D.N.Y. 2013) ("[R]isk disclosures are misleading where the company warns only that a risk may impact its business when that risk has already materialized."). The risk disclosures upon which Defendants rely here provided only vague warnings, without providing the requisite specifics needed to trigger the safe harbor.[25] *See Dodona I, LLC v. Goldman, Sachs & Co.*, 847 F. Supp. 2d 624, 647 (S.D.N.Y. 2012) ("[R]isk disclosures must accurately characterize the scope and specificity of the risk, as understood at the time the statements are made.").

Accordingly, Plaintiffs have adequately alleged Defendants' misstatements and omissions.

## II. THE AC SUFFICIENTLY ALLEGES DEFENDANTS' SCIENTER

Plaintiffs have adequately alleged Defendants' scienter. The PSLRA requires that a plaintiff "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. §78u-4(b)(2). In its analysis, the court "must consider the complaint in its entirety" because the "inquiry . . . is whether ***all*** of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 322-23 (emphasis in original).

[25] *See, e.g.*, App'x B at 2 ("Medicine pipeline and intellectual property risks: failure or delay in delivery of pipeline and new medicines; *failure to meet regulatory or ethical requirements for medicine development or approval*"); *id.* ("*Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond the Group's control, include, among other things: - the risk of failure or delay in delivery of pipeline or launch of new medicines - the risk of failure to meet regulatory or ethical requirements for medicine development or approval . . . - the impact of economic, regulatory and political pressures . . . - the risk of failures or delays in the quality or execution of the Group's commercial strategies . . . - the risk of the safety and efficacy of marketed medicines being questioned . . . .*") (all emphasis in original).

The inference of "scienter need not be irrefutable, *i.e.*, of the 'smoking gun' genre, or even the 'most plausible of competing inferences.'" *Id.* at 324. Rather, an inference of scienter is sufficient if a reasonable person would deem it "at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324. While the court "must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff" (*id.*), "a tie on scienter goes to the plaintiff" at this stage. *Lockheed*, 875 F. Supp. 2d at 372.

A plaintiff can plead scienter "either '[]by alleging facts to show that defendants had both motive and opportunity to commit fraud, or . . . that constitute strong circumstantial evidence of conscious misbehavior or recklessness.'" *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 39 (2d Cir. 2000). "Recklessness may be shown by allegations that defendants knew facts or had access to information suggesting that their public statements were not accurate or failed to check information they had a duty to monitor." *iDreamSky*, 236 F. Supp. 3d at 833. In addition, while generally the most straightforward way to raise an inference of scienter for a corporation is to plead it for an individual defendant whose intent could be imputed to the corporation, it is also possible to plead an inference of corporate scienter without pleading any individual defendant's scienter. *See Teamsters Loc. 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195-96 (2d Cir. 2008).

**A. Defendants Acted Knowingly or Recklessly**

The AC alleges Defendants' pre-Class Period awareness of the dosing error that they had discovered by no later than June 5, 2020 (and most likely earlier), when AZN and Oxford notified health regulators and thereafter changed the trial protocol as a result – a fact they did not disclose to investors. ¶¶42, 139. While Defendants argue that the AC does not plead their actual knowledge of the dosing error, or identify the reports or statements containing this information, *see* MTD at 29-30, the Second Circuit requires only that a plaintiff "[a]llege that defendants knew facts or ***had access*** to information suggesting that their public statements were not accurate." *iDreamSky*, 236 F. Supp. 3d

at 833. The Individual Defendants – AZN's CEO, CFO, and Chief Scientist – undeniably had access to this information, as AZN notified the regulators and changed the trial protocol.[26] Thus, they either knew about these facts[27] – contained in the new trial protocol – or recklessly ignored them when making statements about the status of AZD1222, the trial results, and the inclusion of 55+ subjects, without informing themselves of this information.[28]

Moreover, in the circumstances of this case, it strains credulity that Defendants would not have been aware of an issue so serious that it required notification to the regulators and the trial participants, and a change to the trial protocol, especially when investors and analysts frequently asked about the vaccine. ¶¶52-54, 76; *see, e.g.*, *New Orleans Emps. Ret. Sys. v. Celestica, Inc.*, 455 F. App'x 10, 14 & n.3 (2d Cir. 2011) (scienter pleaded where subject of fraud was "a subject about which investors and analysts often inquired"); *Fresno Cnty. Emps.' Ret. Ass'n v. comScore, Inc.*, 268 F. Supp. 3d 526, 553 (S.D.N.Y. 2017) (that revenue was "a subject about which investors and analysts often inquired . . . reinforces the inference of scienter"); *Pirnik v. Fiat Chrysler Autos., N.V.*, 2016 WL 5818590, at *7 (S.D.N.Y. Oct. 5, 2016) (defendant's statement that he was "tak[ing] a harder look" supported scienter). In fact, Soriot and Pangalos personally made many of the challenged statements about the progress and success of AZD1222 and the inclusion in the trials of 55+ subjects, implying that they had a reasonable basis for making them. *See, e.g.*, ¶¶47, 51-54, 57,

[26] Defendants feign ignorance of the protocol amendment because "the ex-US trials were led by Oxford." MTD at 30. But they fail to contend with the fact that "***[b]oth*** AstraZeneca and Oxford informed health regulators about the half-dose followed by the full-dose error[.]" ¶42; *see also* MTD at 30 ("Moreover, AZ and Oxford informed regulators about the dosing measurement discrepancy").

[27] Additional support for Defendants' knowledge of the error is the fact that a letter, signed by Oxford Professor Andrew J. Pollard, was sent on June 8, 2020 to the trial participants notifying them of the dosing mishap and presenting it as opportunity for Oxford researchers to learn how well the vaccine works at different doses. The letter did not, however, acknowledge any error, nor did it disclose that researchers had reported the issue to British medical regulators, who instructed Oxford to add another test group to receive the full dose – as was intended by the trial's original design. ¶124.

[28] The cases cited by Defendants in support of their scienter argument are unpersuasive as plaintiffs in the cited cases relied on scienter theories that courts in this Circuit have deemed inadequate to allege scienter alone. *See Fialkov v. Alcobra Ltd.*, 2016 WL 1276455, at *7 (S.D.N.Y. Mar. 30, 2016) (no scienter where allegations did not "extend beyond the core operations doctrine"); *Philip Morris*, 2021 WL 4135059, at *13 (rejecting scienter argument "based solely on [defendants'] executive positions").

60, 63, 66, 74-76; *see also Gauquie v. Albany Molecular Rsch., Inc*., 2016 WL 4007591, at *2 (E.D.N.Y. July 26, 2016) ("Actively communicating with the public about [an] issue demonstrates defendants' sensitivity to it" and supports the inference that defendants had knowledge of information contradicting such statements); *Reese v. Malone*, 747 F.3d 557, 572 (9th Cir. 2014) ("[b]y making a detailed factual statement, contradicting important data to which she had access, a strong inference arises that she knowingly misled the public as to its clear meaning"), *overruled on other grounds by City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc*., 856 F.3d 605 (9th Cir. 2017); *SEB Inv. Mgmt. AB v. Endo Int'l, PLC*, 351 F. Supp. 3d 874, 906 (E.D. Pa. 2018) ("[Defendants'] public comments regarding the clinical data in press releases and earnings calls confirm they had intimate knowledge of the data. Indeed, that is what they wanted the public, particularly investors, to think. These officers were speaking as authoritative sources who possessed the information to support their statements."); *In re PTC Therapeutics, Inc. Sec. Litig*., 2017 WL 3705801, at *16-*17 (D.N.J. Aug. 28, 2017) (finding "powerful evidence of scienter" where defendants spoke "explicitly and repeatedly" about drug trials, and defendants' "statements to investors . . . implied that they had first-hand knowledge of [the study] results and PTC's conversations with the FDA").[29]

The inference of scienter is further buttressed by the importance of the vaccine to both the Company and the world at large, and the Individual Defendants' corporate positions and active involvement in overseeing and publicly communicating the development of AZD1222. AZN was one of several pharmaceutical companies racing to develop a vaccine to treat the world's worst pandemic in a century, which subjected it to intense scrutiny by experts, regulators, and the media. It is reasonable to infer that AZD1222 was the subject of close internal scrutiny by AZN senior

[29] Thus, this is case is distinguishable from *Tung v. Bristol-Myers Squibb Co.*, 412 F. Supp. 3d 453, 460 (S.D.N.Y. 2019), where the plaintiff generically alleged that defendants' skill or experience imputed scienter to them.

executives, and the adverse undisclosed facts about AZN's vaccine candidate would invariably be a focal point of any senior executives' attention, especially in a biopharmaceutical company trying to be at the forefront of the development of a Covid vaccine. *See, e.g.*, *In re Sequans Commc'ns S.A. Sec. Litig.*, 2019 WL 4805072, at *2 (E.D.N.Y. Sept. 30, 2019) (finding scienter as to the defendant CEO, given that he "was personally involved" in matters); *In re Mylan N.V. Sec. Litig.*, 2018 WL 1595985, at *12 (S.D.N.Y. Mar. 28, 2018) (Oetken, J.) (finding that "it require[d] no stretch of the imagination to infer that, due to their positions at the company and the importance of EpiPen to [the company's] operations, [the individual defendants] 'knew facts or had access to information suggesting that their public statements' about the EpiPen rebate rate and the existence of adverse regulatory activity 'were not accurate'"); *Ark. Tchr. Ret. Sys. v. Bankrate, Inc.*, 18 F. Supp. 3d 482, 486 (S.D.N.Y. 2014) (defendants' personal involvement "directing hands-on efforts" to solve a company problem supported a "strong plausible inference of scienter"); *Lockheed*, 875 F. Supp. 2d at 371 ("[I]f 'a plaintiff can plead that a defendant made false or misleading statements when contradictory facts of critical importance to the company either were apparent, or should have been apparent, an inference arises that high-level officers and directors had knowledge of those facts by virtue of their positions with the company.'"). Therefore, both the importance of the vaccine, and Defendants' active involvement, as evidenced by the frequency they spoke about the vaccine, support scienter.[30]

Considered holistically, these facts raise a strong inference of scienter.

**B. Defendants Were Motivated to Conceal Material Facts About AZD1222**

In addition, although motive is not required to sufficiently allege scienter, *see Lockheed*, 875

[30] Contrary to Defendants' argument (MTD at 31), Plaintiffs do not invoke the core operations doctrine, distinguishing this case from *Tung*, 412 F. Supp. 3d at 460 n.3. Rather, using common sense and drawing all inferences in Plaintiffs' favor, it is reasonable to infer that, under the unique circumstances of the Covid pandemic in the spring of 2020, Defendants were aware of the status of AZN's vaccine trials. *See Inst'l Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 272-73 (3d Cir. 2009) ("In assessing the allegations holistically as required by *Tellabs*, the federal courts certainly need not close their eyes to circumstances that are probative of scienter viewed with a practical and common-sense perspective.").

F. Supp. 2d at 371, the AC adequately alleges that Defendants were motivated to misrepresent the status and results of AZN's AZD1222 trials, the progress of the vaccine's development, and the immune response in patients over age 55 in order to: (i) fund AZN's December 2020 acquisition of Alexion, its largest ever, with AZN's fraudulently inflated stock price (¶140); and (ii) develop a viable Covid vaccine in order to obtain the prestige that would come with it and avoid reputational or financial harm that may arise from a failure to do so (¶¶136-137).[31]

These motive allegations are sufficient. *See, e.g., In re Vivendi Universal, S.A. Sec. Litig.*, 381 F. Supp. 2d 158, 185 (S.D.N.Y. 2003) (motive sufficiently alleged where defendants "were motivated to commit fraud so they could acquire and continue acquiring companies . . . by using its artificially inflated stock and ADSs as currency"); *Hull v. Glob. Digit. Sols., Inc.*, 2017 WL 6493148, at *20 (D.N.J. Dec. 19, 2017) ("[I]mportantly, when corporate defendants materially misrepresent the financial status of a company to enable stock-based business acquisitions at the time of the alleged misrepresentations, that alleged motive can give rise to a strong inference of scienter"); *In re ATI Techs., Inc., Sec. Litig.*, 216 F. Supp. 2d 418, 440 (E.D. Pa. 2002) (finding motive in stock-based acquisitions during period of alleged misstatements). At a minimum, these facts bolster the inference of scienter.[32]

Contrary to Defendants' claim (MTD at 28), "[i]nsider trading is by no means the only way to allege scienter by raising motive." *Norfolk Cnty. Ret. Sys. v. Ustian*, 2009 WL 2386156, at *10 (N.D. Ill. July 28, 2009). Moreover, Defendants' argument regarding insider trading is misleading. Defendants argue that "AZ's SEC disclosure regarding CEO and CFO compensation shows that

[31] Defendants argue that given the microscope that AZN was under regarding the creation of AZD1222, "any motive to commit fraud *in full world* view strains credulity." MTD at 28 (emphasis in original). To the contrary, it adds to motive: because the pressure of being in full world view motivated Defendants to conceal the truth about their failures from the public.

[32] *ECA & Local 134*, is inapposite, because there, "the alleged misstatements began eight years before the acquisition and ended years afterward render[ing] any connection between the events dubious at best." 553 F.3d at 201.

Messrs. Soriot and Dunoyer's AZ holdings increased over 2020." MTD at 28. This suggests that they were increasing their holdings during the Class Period. But Defendants omit that the increase in holdings occurred ***exclusively prior to the Class Period*** in 2020, and Soriot and Dunoyer did not buy any AZN stock during the Class Period.[33] *See* Walsh Decl. Ex. C (attaching AZN Forms 6-K).[34] If anything, the lack of insider trading allegations is a neutral factor. *See In re Reserve Fund Sec. & Derivative Litig.*, 732 F. Supp. 2d 310, 320 n.6 (S.D.N.Y. 2010) (rejecting argument that absence of insider sales negates allegations of fraudulent intent).[35]

### C. Plaintiffs Have Adequately Alleged Corporate Scienter

Because the AC adequately alleges scienter against the Individual Defendants, it has alleged scienter against AZN as well. *See, e.g.*, *Dynex*, 531 F.3d at 195. In addition, "it is possible to raise the require[d] inference with regard to a corporate defendant without doing so with regard to a specific individual defendant." *Id*. The knowledge of whomever communicated with the regulator about the protocol change is imputed to AZN. *See* ¶42 ("***Both*** AstraZeneca and Oxford informed health regulators about the half-dose followed by the full-dose error, and it was concluded that the study protocol should be amended to include recipients of this regimen[.]").[36] Given the importance of the Covid vaccine to both AZN and the world, it is reasonable to infer that such communications were made by senior executives, whose scienter can be imputed to AZN. *See In re Moody's Corp. Sec. Litig.*, 599 F. Supp. 2d 493, 515-16 (S.D.N.Y. 2009) ("There is no formulaic method or

[33] Because Defendants did not increase their holdings during the Class Period, *Tung*, 412 F. Supp. 3d at 459, is inapt.

[34] In fact, the only transaction during the Class Period by Soriot or Dunoyer was a gift from Soriot to his family members, which decreased his AZN holdings. *See* Walsh Decl. Ex. C at 17.

[35] Defendants' reliance on *Borochoff v. GlaxoSmithKline PLC*, 2008 WL 2073421, at *8 (S.D.N.Y. May 9, 2008), is also misplaced. There, unlike here, the defendant disclosed the allegedly omitted information to both the FDA ***and investors***, whereas here, Defendants disclosed the omitted information only to the health regulators. *See id.* Further, Defendants provide the following misleading parenthetical for *Borochoff*: "('Allegations of defendants' intent to defraud by suppressing negative data are inconsistent with defendants' disclosure of that data . . . to the FDA.')." MTD at 30. Significantly, the ellipses omit that the information was disclosed "on GSK's website" in addition to the FDA, such that investors would have been put on notice of the information. *Borochoff*, 2008 WL 2073421, at *8.

[36] Despite arguments that the disclosure to regulators and protocol amendment undermine an inference of scienter, *see* MTD at 30, the disclosure and amendment do not relieve Defendants of their disclosure obligations to investors.

seniority prerequisite for employee scienter to be imputed to the corporation, but scienter by management-level employees is generally sufficient to attribute scienter to corporate defendants.").[37]

## III. THE AC SUFFICIENTLY ALLEGES LOSS CAUSATION

Plaintiffs have adequately alleged loss causation. A plaintiff's burden to plead loss causation "is not a heavy one." *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 187 (2d Cir. 2015). To plead loss causation, all that is required is a "short and plain statement" that provides "some indication of the loss and the causal connection that the Plaintiff has in mind." *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 346-47 (2005). The "ultimate issue is whether the defendant's misstatement, as opposed to some other fact, foreseeably caused the plaintiff's loss" – and "there are an infinite variety of ways for a tort to cause a loss." *Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1210 (9th Cir. 2016).

The AC pleads with the requisite detail the newly revealed information that exposed the falsity of Defendants' prior misrepresentations and caused the resulting loss. *See, e.g.*, ¶¶78-123, 141-142. Contrary to Defendants' argument, *see* MTD at 33, on November 23, 2020, AZN

[37] Defendants argue that the inference of non-fraudulent intent is the more compelling inference. MTD at 31-32. For instance, Defendants mischaracterize Plaintiffs' claims, asserting that "Plaintiffs would have this Court believe that [AZN] would invest billions of dollars to develop a vaccine it knew would not be approved based on clinical trials it knew were flawed." MTD at 1. To the contrary, Plaintiffs do not allege that Defendants knew the vaccine would not be approved. Rather, Plaintiffs allege that Defendants knowingly or recklessly made material misstatements and omissions concerning a manufacturing error resulting in a material change in the trial protocol, and the trial's exclusion of sufficient amounts of subjects over 55 years of age required to assess efficacy. *See supra* at 13-21, 27-31. Further, Defendants' base their argument on facts outside of the AC and ignore the allegations in Plaintiffs' well-pled complaint. *First*, Defendants attempt to paint AZN as only following the direction of Oxford. MTD at 31. But the AC is replete with allegations regarding the active role that AZN took in developing the AZD1222 vaccine. *See, e.g.*, ¶¶31, 138. *Second*, Defendants assert that the trials were conducted with "transparency and care." MTD at 31. But the AC alleges that Defendants were not as transparent with investors as they would have the Court believe. *See, e.g.*, ¶¶69, 91, 124-125, 127-131. *Third*, Defendants argue that the "vaccine was successfully developed" with "approvals around the world." MTD at 31. Such arguments ignore the public backlash against their trials, their omissions to investors, and the related hurdles Defendants faced with respect to regulatory approval. *See, e.g.*, ¶¶82-91, 95-99, 106-113, 116-118, 120-122. *Finally*, Defendants argue that the vaccine was developed at "no profit, and undertaking manufacturing costs at risk should authorizations or approvals not come." MTD at 32. This ignores that AZN's development and manufacturing of the vaccine was government-funded (¶¶35, 38, 65), and that AZN intended to make a profit post-pandemic (¶36; Walsh Decl. Ex. A). Indeed, AZN has now announced a shift from the non-profit model and expects "some earnings contribution from new orders in the fourth quarter of this year" (Walsh Decl. Ex. A). Thus, Plaintiffs' inference of scienter is at least as compelling as Defendants' asserted inference. *See Odonate*, 2021 WL 3406271, at *8 ("It is plausible that Defendants were ensuring the health of their CONTESSA trial patients while simultaneously misleading their investors by failing to disclose that material information.").

disclosed for the first time the dosing error to investors that it had known about prior to the Class Period and, the next day, disclosed that the LD/SD cohort did not include patients over the age of 55. ¶¶78, 82; *see also supra* at 18 n.13. The price of AZN ADSs declined by 5% in response, on abnormally high volume. ¶92; *see also Pearlstein v. BlackBerry Ltd.*, 2021 WL 253453, at *18 (S.D.N.Y. Jan. 26, 2021) (a disclosure need not be a "mirror image").

On December 14, 2020, the *Daily Mail* quoted Pangalos as saying, "There is no doubt I think that we would have run the study a little bit differently if we had been doing it from scratch." ¶114. In response, AZN ADSs fell by approximately 8%. *Id.* On January 26, 2021, two news articles quoted sources in the German government as saying the AZN vaccine was less than 10% effective in people over 65 years old, and regulatory approval was in jeopardy. ¶118. Additional news was disclosed regarding the vaccine's ineffectiveness on older populations, and in response, the price of AZN ADSs declined by 7%. ¶¶119-123. Thus, Plaintiffs plausibly allege that Defendants' statements surrounding their clinical trials "concealed the circumstances that bear upon the loss suffered such that plaintiffs would have been spared all or an ascertainable portion of that loss absent the fraud." *Mylan*, 2018 WL 1595985, at *18.

Defendants' argument that the relevant information was already disclosed by the time of the additional revelations in late January 2021 (*i.e.*, the report citing a lack of elderly patients and German regulators rejecting the vaccine for approval) is meritless. MTD at 34. These events were additional materializations of the risk that had been concealed by Defendants during the Class Period. *See Allergan*, 2019 WL 4686445, at *29 (holding that loss causation was adequately pled when the risk materialized through events other than affirmative statements by the defendant).

Further, Defendants' arguments raise a fact-intensive disaggregation issue (*see* MTD at 33) that should be reserved for after the pleading stage. *See, e.g.*, *Allergan*, 2019 WL 4686445, at *29

("Whether [Allergan's ADS] price fell because of the revelation of a fraud (as opposed to a negative development affecting the Company's business) [or other non-fraud reason] is a fact question."); *Delcath*, 36 F. Supp. 3d at 336 (rejecting defendants' loss causation argument that stock price dropped solely because of FDA non-approval and not from any alleged fraud because "[t]his is a factual argument for a later day and does not diminish the sufficiency of the Complaint").

## IV. THE COURT SHOULD REJECT DUNOYER'S ARGUMENTS FOR DISMISSAL

Defendants argue that claims against Dunoyer should be dismissed because he did not make a false statement pursuant to *Janus Capital Group, Inc. v. First Derivative Traders*, 564 U.S. 135 (2011). *See* MTD at 34-35. To the contrary, Dunoyer was a "maker" of numerous alleged misstatements because, as CFO, he had direct involvement in the everyday business of AZN and exercised "ultimate authority over the statement[s]" it issued publicly. *Janus*, 564 U.S. at 142. Plaintiffs may rely on the group-pleading doctrine for Dunoyer, "which allows a plaintiff to rely on a presumption that written statements that are 'group-published,' *e.g.*, SEC filings and press releases, are statements made by all individuals with direct involvement in the everyday business of the company."[38] *In re Cannavest Corp. Sec. Litig.*, 307 F. Supp. 3d 222, 240 (S.D.N.Y. 2018). "[M]ost judges in this District have continued to conclude that group pleading is alive and well [after *Janus*]." *Id.* at 241. Thus, Dunoyer made statements in group-published documents.

Dunoyer's argument that he lacks scienter, and thus lacks culpable participation, is also without merit. *See* MTD at 27-32, 35. As discussed above, the Individual Defendants knew of, or recklessly disregarded, the alleged omissions. *See supra* at 28-31. Because Plaintiffs have adequately pled scienter under Section 10(b) for Dunoyer, Plaintiffs have also adequately pled his culpable participation[39] under Section 20(a).[40]

[38] The group-published misstatements are alleged in ¶¶44, 47, 49-50, 57, 60-61, 63, 70, 72-73.

[39] Some courts in this District have found that culpable participation is not required. *See In re ShengdaTech, Inc. Sec.*

## V. THE COURT SHOULD STRIKE OR DECLINE TO CONSIDER MATERIALS SUBMITTED BY DEFENDANTS THAT ARE OUTSIDE OF THE AC

In their Motion, Defendants attempt to distract from the well-pled allegations of the AC, which must be credited at this stage, and instead introduce facts constructed from self-selected outside sources such as articles, press releases, and conference call and interview transcripts, many of which post-date the Class Period. Defendants use these extraneous materials in an attempt to make the Phase II/III trials appear more successful than they actually were, and to divert from the misrepresentations and omissions made about the clinical trials during the Class Period. An appendix listing and describing the extraneous materials is annexed to the Walsh Decl. as Exhibit D. Because those sources came into existence ***after*** the Class Period, they could not have been incorporated into the AC or been relied on in drafting it, and cannot be considered now. *See City of Austin Police Ret. Sys. v. Kinross Gold Corp.*, 957 F. Supp. 2d 277, 287 (S.D.N.Y. 2013) (refusing to consider disputed exhibits that were not "integral to, relied upon, attached to, or referenced in the [c]omplaint"). Nor may the Court consider these materials for their truth regarding developments post-Class Period – the only conceivable reasons why Defendants cite them. *See Roth v. Jennings*, 489 F.3d 499, 510 (2d Cir. 2007). Rather, the Court should disregard or strike those exhibits and any references in the briefing to them. *See City of Sterling Heights Police & Fire Ret. Sys. v. Kohl's Corp*., 2015 WL 1478565, at *3-*5 (E.D. Wis. Mar. 31, 2015) (striking SEC filings and articles, and references to such exhibits in briefs, and denying dismissal due to heavy reliance on those exhibits). Defendants may not rewrite a complaint with their own purported facts. *See In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 333 (S.D.N.Y. 2003) (defendants must take complaint "as [it is] written").

*Litig.*, 2014 WL 3928606, at *10 (S.D.N.Y. Aug. 12, 2014) (compiling cases); *see also Menaldi v. Och-Ziff Cap. Mgmt. Grp. LLC*, 164 F. Supp. 3d 568, 587 (S.D.N.Y. 2016) (Oetken, J.) (acknowledging that the law remains unsettled).

[40] Defendants' sole argument for dismissing the Section 20(a) claims as to Soriot and Pangalos is because, in their view, Plaintiffs failed to allege a primary Section 10(b) violation. Since Plaintiffs have adequately alleged a Section 10(b) claim, the Section 20(a) claim should also be sustained as to all of the Individual Defendants.

## CONCLUSION

For all the above reasons, Defendants' Motion to dismiss should be denied in its entirety.[41]

DATED: December 10, 2021

Respectfully submitted,

POMERANTZ LLP
JEREMY A. LIEBERMAN
MURIELLE J. STEVEN WALSH
ERIC D. GOTTLIEB

*/s/ Murielle J. Steven Walsh*
MURIELLE J. STEVEN WALSH

600 Third Avenue
New York, NY 10016
Telephone: 212/661-1100
212/661-8665 (fax)
jalieberman@pomlaw.com
mjsteven@pomlaw.com
egottlieb@pomlaw.com

ROBBINS GELLER RUDMAN
& DOWD LLP
SAMUEL H. RUDMAN
ALAN I. ELLMAN
WILLIAM J. GEDDISH
MAGDALENE ECONOMOU
58 South Service Road, Suite 200
Melville, NY 11747
Telephone: 631/367-7100
631/367-1173 (fax)
srudman@rgrdlaw.com
aellman@rgrdlaw.com
wgeddish@rgrdlaw.com
meconomou@rgrdlaw.com

[41] Should the Court find that the AC contains deficiencies, Plaintiffs respectfully request leave to amend. *See* Fed. R. Civ. P. 15(a)(2). Granting leave to amend is often appropriate when granting a motion to dismiss for failure to state a claim, *see Van Buskirk v. N.Y. Times Co.*, 325 F.3d 87, 91 (2d Cir. 2003), and Defendants have not pointed to any compelling reason why leave to amend should be denied. *See Loreley*, 797 F.3d at 190 ("[w]ithout the benefit of a ruling, many a plaintiff will not see the necessity of amendment or be in a position to weigh the practicality and possible means of curing specific deficiencies.").

POMERANTZ LLP
PATRICK V. DAHLSTROM
10 South LaSalle Street, Suite 3505
Chicago, IL 60603
Telephone: 312/377-1181
312/377-1184 (fax)
pdahlstrom@pomlaw.com

*Attorneys for Lead Plaintiffs*

VANOVERBEKE, MICHAUD TIMMONY, P.C.
THOMAS C. MICHAUD
79 Alfred Street
Detroit, MI 48201
Telephone: 313/578-1200
313/578-1201 (fax)
tmichaud@vmtlaw.com

*Additional Counsel for Lead Plaintiff Wayne County Employees' Retirement System*

PORTNOY LAW FIRM
LESLEY F. PORTNOY
1800 Century Park East, Suite 600
Los Angeles, CA 90067
Telephone: 310/692-8883

*Additional Counsel for Lead Plaintiff Nuggehalli Balmukund Nandkumar*

BRONSTEIN, GEWIRTZ
& GROSSMAN, LLC
PERETZ BRONSTEIN
60 East 42nd Street, Suite 4600
New York NY 10165
Telephone: 212/697-6484
212/697-7296 (fax)
peretz@bgandg.com

*Additional Counsel for Additional Plaintiff Vladimir Zhukov*

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on December 10, 2021, I authorized a true and correct copy of the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such public filing to all counsel registered to receive such notice.

*/s/ Murielle J. Steven Walsh*

MURIELLE J. STEVEN WALSH

POMERANTZ LLP
600 Third Avenue
New York, NY 10016
Telephone: 212/661-1100
212/661-8665 (fax)